RESPONSE

In response to the Office Action of September 13, 2004, Applicant through his attorney hereby responds as follows.

The Examiner Rejects Claims 1-5, 7-10, 13-21, 24, 25, and 29-33 under 35 USC 103(a) on the basis of EPO 0 754 452 A2 to Hatano et al ("HATANO"). This rejection is respectfully traversed as follows. HATANO teaches a coated capsule comprising 3 components: i.e. a hard capsule, a polymer film soluble at low pH and an enteric coating film. The descriptions and all of the examples of HATANO clearly show that two separate coatings on the hard capsule are required. The Examiner argues that HATANO teaches (pg. 8, lines 38-40) that an intermediate layer can be provided suggesting this is an optional component. The Examiner has misinterpreted HATANO. Lines 38-40 actually suggests an intermediate layer comprising a medicament and a water soluble polymer may be added **between** the low pH –soluble layer and the enteric coated film. This is, therefore, an **additional** coating layer not an elimination of one of the two coated films applied successively to the core capsule as described in HATANO. Thus, nothing in HATANO teaches how to create a useable product with a single aqueous coating. In contrast to HATANO, the Claims of the present invention currently under consideration teach a product with an enteric or colonic coated layer that can be applied directly to the HPMC capsule substrate (the core capsule) without any intermediate layer or low pH-soluble coating layer as required by HATANO. The current Claims are specifically limited to a **single aqueous coating**.

The Examiner also rejects Claims 6, 11 and 12 under 35 USC 103(a) on the basis of HATANO as described above and further in view of WO 95/35100 to Watts ("WATTS"). This rejection is traversed as follows. The rejection based on HATANO is traversed for the reasons previously explained above. The rejection based on WATTS is traversed as follows. WATTS teaches colonic coating of **injection molded starch capsules**. All of the examples of WATTS teach the use of a " pre-coat" or "subcoat" to the starch capsule substrate prior to application of the functional colonic coating. This follows accepted practice in the

pharmaceutical industry of providing a subcoat to allow the final functional coat to bind more effectively to the surface of the subcoat. This technique is practiced widely particularly for gelatin capsules where adhesion to the capsule surface is a known problem. WATTS teaches the use of an injection molded starch capsule. WATTS **does not teach** either (i) an HPMC capsule or (ii) coating an HPMC capsule with a single aqueous coating. Additionally, as previously noted above, none of the examples of WATTS describe a capsule with a single coating or how that could be accomplished. Finally, the combination of HATANO and WATTS is also incorrect since WATTS is limited to injection molded starch capsules.

With regard to the present invention, the advantages of a single functional coating include (1) reduced processing time and errors, (2) lower cost and (3) possibly reduced risk of interaction of subcoatings with the desired functional coating behavior (note HATANO's comment on the influence of the subcoat on dissolution lag time).

Further, the direct application of an enteric and colonic functional polymer coating onto an HPMC capsule substrate is not obvious. It has been previously explained that the industry practice as well as HATANO and WATTS use a subcoat or additional coat before applying the final functional coating.

It is respectfully submitted that the rejections have been overcome for the reasons explained above and on the basis of the Amendment listed herein. An early Notice of Allowability is respectfully requested.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the number listed below.

Respectfully submitted,

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